Docket No.: 12780/101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PLICANT

Leonard et al.

SERIAL NO.

09/708,352

FILED

November 8, 2000

FOR

VACCINES FOR MYCOPLASMA BOVIS AND

METHODS OF USE

EXAMINER:

Ford

GROUP ART UNIT:

1645

Mail Stop: PETITION Commissioner for Patents

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I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop: Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

Date:

Signature:

PETITION UNDER 37 C.F.R. §181

SIR:

Petitioners request that the Notification of Non-compliant Appeal Brief, issued February 5, 2008 (Exhibit A), be withdrawn.

The Notification of Non-compliant Appeal Brief stated that the Appeal Brief filed May 22, 2006 (Exhibit B) failed to comply with 37 C.F.R. §§41.37 and 1.116(e) because pages 15-18 of the Appeal Brief contained new arguments and new evidence filed after the Office Action containing a final rejection. See page 2 of the Notification of Non-compliant Appeal Brief:

The Appeal Brief filed on 26 May 2006 is defective for failure to comply with one or more provisions of 37 CFR 41.37.

The Appeal Brief filed on May 26, 2006 acknowledges that the after-final amendment filed October 24, 2005 was not perferred. However, Applicant has presented arguments in the Appeal Brief that have not been previously considered. See pages 15-18 of the Appeal Brief, Applicant is advised that the affidavit or other evidence, e.g. new arguments filed after the final action, but before or on the date of filing a Notice of Appeal will not be entered because Applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.16(e).

The Petitioners respectfully submit that the Notification of Non-compliant Appeal Brief was issued in error and request that it be withdrawn because:

- (1) Only new evidence, not new arguments, is forbidden by 37 C.F.R. §41.37 and 1.116(e). The Appeal brief contains no new evidence.
- (2) Even if new arguments were forbidden, the Appeal Brief contains no new arguments.

The Appeal Brief contains no new evidence

37 C.F.R. §§41.37 and 1.116(e), cited as support for the issuance of the Notification of Non-compliant Appeal Brief, do not mention "new arguments." It would make no sense to rule out a new argument, or a restatement in different terms of a prior argument, in an appeal brief. Otherwise, the appeal brief would serve little function. The Board could simply read the Appellants' prior Office Action response, and there would be little point to asking the Examiner to supply an answer. The arguments in the final rejection would be sufficient.

37 C.F.R. §41.37(c)(2) states:

(2) A brief shall not include any new or non-admitted amendment, or any new or non-admitted affidavit or other evidence. See § 1.116 of this title for amendments, affidavits or other evidence filed after final action but before or on the same date of filing an appeal and § 41.33 for amendments, affidavits or other evidence filed after the date of filing the appeal.

37 C.F.R. §116(e) states:

(e) An affidavit or other evidence submitted after a final rejection or other final action (§ 1.113) in an application or in an *ex parte* reexamination filed under § 1.510, or an action closing prosecution (§ 1.949) in an inter partes reexamination filed under § 1.913 but before or on the same date of filing an appeal (§ 41.31 or § 41.61 of this title), may be admitted upon a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented.

37 C.F.R. §41.37(c)(2) refers to "new or non-admitted amendment, or any new or non-admitted affidavit or other evidence" and 37 C.F.R. §116(e) refers to "an affidavit or other evidence submitted after a final rejection or other final action." Pages 15-18 of the Appeal Brief contain no amendment to the specification or claims, no affidavit, and no new citation of evidence. Thus, 37 C.F.R. §41.37(c)(2) and 37 C.F.R. §116(e) provide no support for the issuance of the Notification of Noncompliant Appeal Brief.

The Notification of Non-compliant Appeal Brief did not specify which item or items on page 15-18 was considered to be new evidence. The evidence appendix of the Appeal Brief lists 8 items. Items 1-4 and 6-8 are listed together with citations to where those items appeared in the record. Each of items 1-4 and 6-8 appeared in the

record before the final rejection was issued. Accordingly, none of items 1-4 and 6-8 can be considered new evidence.

Item 5 is a copy of Ex parte Hervy A. Morris, an unpublished decision by the Board of Patent Appeals & Interferences, which was discussed on pages 15-18.

Because this decision did not appear in United States Patents Quarterly, a copy of this decision was provided as an exhibit in the Amendment After Final, as a courtesy to the Examiner. That Ex parte Hervy A. Morris was provided as an exhibit in order to make it easier for the Examiner to review this decision does not change the fact that Ex parte Hervy A. Morris is case law, not new evidence. Thus, the Appellants should not be precluded from relying on Ex parte Hervy A. Morris in their Appeal Brief.

Additional considerations arguing for the inclusion of Ex parte Hervy A.

Morris are that (1) all relevant case law should be made available to the Board of
Patent Appeals & Interferences and (2) the Examiner will have an opportunity to
address Ex parte Hervy A. Morris in the Examiner's Answer.

These considerations argue for the inclusion of *Union Oil Co. of Cal. v.*Atlantic Richfield Co., 208 F. 3d 989, 54 U.S.P.Q. 2d 1227 (Fed. Cir. 2000) in the Appeal Brief as well. It would be absurd to deny the Appellants the opportunity to rely on, and to deny the Board the benefit of considering, legal authority merely because such authority was not previously cited to the Examiner.

Union Oil, like Ex parte Hervy A. Morris, is a case that is discussed on pages 15-18 of the Appeal Brief.

The Appeal Brief does not contain new arguments

Pages 15-18 of the Appeal Brief are directed to an argument that was discussed in an Amendment filed before the Office Action containing a final rejection was issued. That argument is directed to whether certain functional language in the claims ("protective against *Mycoplasma bovis* mastitis") is a real limitation of the claims that serves to distinguish the claims over the prior art. See, e.g., the Amendment filed March 29, 2004 (Exhibit C), at page 15:

This recitation makes clear that the functional characteristic of being protective against mastitis is not simply an intended use but rather is a characteristic of the vaccine itself. This characteristic distinguishes over the prior art, such as the vaccine disclosed in Boothby.

The Office Acton containing the final rejection (Exhibit D) issued May 25, 2005. Thus, this argument was clearly part of the record long before the final rejection and the Petitioners were entitled to include it in their Appeal Brief.

Except for the last portion of page 18, which will be discussed later, all of the discussion on pages 15-18 of the Appeal Brief is directed to this argument over the meaning of the functional language "protective against *Mycoplasma bovis* mastitis."

Page 15 of the Appeal Brief begins with a discussion of *Union Oil Co. of Cal.* v. Atlantic Richfield Co., 208 F. 3d 989, 54 U.S.P.Q. 2d 1227 (Fed. Cir. 2000), in which Petitioners argue that *Union Oil* supports their position with respect to the argument over the disputed claim language because *Union Oil* dealt with a similar issue concerning the effect of functional language in claims, albeit in a different field of technology. See page 15, first sentence:

A much more recent decision, in the Federal Circuit, which specifically dealt with functional characteristics of product claims, and which is therefore particularly applicable to the present application is *Union Oil*

Co. of Cal. v. Atlantic Richfield Co., 208 F. 3d 989, 54 U.S.P.Q. 2d 1227 (Fed. Cir. 2000).

The Appeal Brief then quoted from portions of *Union Oil* that the Petitioners believe support their position on the disputed claim language. The Petitioners then went on to state, near the top of page 16: "As in *Union Oil*, claims 29, 30, and 40-44 of the present application recite the functional characteristic at issue – 'protective against *Mycoplasma bovis* mastitis,' "leaving no doubt that this portion of the Appeal Brief is directed to an argument about the disputed claim language that had already been raised in the Amendment filed March 29, 2004.

The Petitioners then used the remaining portion of page 16 to quote portions of the specification that support their arguments with respect to the disputed claim language.

Pages 17 and 18 were directed to a discussion of another case, *Ex parte Hervy A. Morris* (available at 1998 WL 1736155), which was also cited to support Petitioners' position on the issue of the disputed claim language concerning protection against mastitis. Following the discussion of *Hervy A. Morris*, at the middle of page 18, the Petitioners summed up this portion of the Appeal Brief by stating: "The evidence of record shows that Boothby I's vaccines were not 'capable of performing the intended use' because the evidence of record shows that Boothby I's vaccines were not protective against mastitis." Again, it is clear that the discussion pertains to the argument over the disputed claim language relating to protection against mastitis.

The last portion of page 18 of the Appeal Brief does not pertain to the argument over the disputed claim language relating to protection against mastitis. However, the material in the last portion of page 18 appeared on page 16 of the

Amendment filed March 29, 2004 (Exhibit C), before the issuance of the Office Action containing a final rejection on May 25, 2005. The corresponding portions of page 18 of the Appeal Brief and page 16 of the Amendment filed March 29, 2004 are as follows:

Appeal Brief

Claims 52 and 55

Claims 52 and 55 recite that the vaccine comprises an adjuvant selected from a group that does not include the adjuvants listed in Boothby I.² Therefore, Boothby I does not anticipate claims 52 and 55.

Amendment filed March 29, 2004

New independent claim 52 recites that the vaccine comprises an adjuvant that differs from the adjuvants listed in Boothby. Therefore, Boothby does not anticipate new claim 52. New claim 55 depends from new claim 52 and therefore Boothby does not anticipate new claim 55 either.

At page 131, Boothby discloses the use of the following adjuvants:
Freund's incomplete adjuvant
N-acetylmuramyl-L-alanyl-D-isoglutamine (MDP)
Amphotericin B
Combined magnesium/aluminum hydroxide
Killed Bordatella periussis

In view of the above, it is clear that pages 15-18 of the Appeal Brief do not include new arguments.

That the argument discussed at pages 15-18 of the Appeal Brief was also discussed in the Amendment After Final does not change the fact that this argument

At page 131, Boothby I discloses the use of the following adjuvants: Freund's incomplete adjuvant
N-acetylmuramyl-L-alanyl-D-isoglutamine (MDP)
Amphotericin B
Combined magnesium/aluminum hydroxide
Killed Bordatella pertussis

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had been raised by the Petitioners long before the final rejection issued and thus is not

a new argument. It defies common sense to hold that reiterating in an Amendment

After Final an argument previously made before the final rejection somehow serves to

convert that argument from an old argument to a new argument.

In view of the above, it is respectfully requested that the Notification of Non-

compliant Appeal Brief be withdrawn.

It is believed that no fee is required for this Petition. If this is in error, please

charge any required fee to Kenyon & Kenyon's Deposit Account No. 11-0600.

The Petitioners hereby make a Conditional Petition for any relief available to

correct any defect seen in connection with this paper, or any defect seen to be

remaining in this application after this paper. The Commissioner is authorized to

charge Kenyon & Kenyon's Deposit Account No. 11-0600 for the Petition fee and

any other fees required to effect this Conditional Petition.

Respectfully submitted,

Date: March ,2008

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APPEICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708.352	F1/08/2000	Joan D. Leonard	### ##################################	
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			FORD, VANESSA I.	
NEW YORK, NY 10004			ARTUNH	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

PTOL-90A (Rev. 04/07)

		Application No.	Applicant(s)			
Notification of Non-Compliant Appeal Brief (37 CFR 41.37)		09/708,352	LEONARD ET AL.			
		Examiner	Art Unit			
	•	Vanessa L. Ford	1645			
· <u></u>	-The MAILING DATE of this communication app	pears on the cover sheet with the	correspondence address			
The Ap	peal Brief filed on <u>26 May 2006</u> is defective for t	failure to comply with one or mor	e provisions of 37 CFR 41.37.			
1205.0	id dismissal of the appeal, applicant must file and 3) within ONE MONTH or THIRTY DAYS from t ISIONS OF THIS TIME PERIOD MAY BE GRA	the mailing date of this Notification				
1.	The brief does not contain the items required unheading or in the proper order.	under 37 CFR 41.37(c), or the ite	ms are not under the proper			
2. 🗌	The brief does not contain a statement of the status of all claims, (e.g., rejected, allowed, withdrawn, objected to, canceled), or does not identify the appealed claims (37 CFR 41.37(c)(1)(iii)).					
3.	At least one amendment has been filed subsequent to the final rejection, and the brief does not contain a statement of the status of each such amendment (37 CFR 41.37(c)(1)(iv)).					
4. 🗍	(a) The brief does not contain a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number and to the drawings, if any, by reference characters; and/or (b) the brief fails to: (1) identify, for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function and step plus function under 35 U.S.C. 112, sixth paragraph, and/or (2) set forth the structure, material, or acts described in the specification as corresponding to each claimed function with reference to the specification by page and line number, and to the drawings, if any, by reference characters (37 CFR 41.37(c)(1)(v)).					
5. 🗌	The brief does not contain a concise statement of each ground of rejection presented for review (37 CFR 41.37(c)(1)(vi))					
6.	The brief does not present an argument under a separate heading for each ground of rejection on appeal (37 CFR 41.37(c)(1)(vii)).					
7. 🗀	The brief does not contain a correct copy of the appealed claims as an appendix thereto (37 CFR 41.37(c)(1)(viii)).					
8. 🗍	The brief does not contain copies of the evidence submitted under 37 CFR 1.130, 1.131, or 1.132 or of any other evidence entered by the examiner and relied upon by appellant in the appeal , along with a statement setting forth where in the record that evidence was entered by the examiner, as an appendix thereto (37 CFR 41.37(c)(1)(ix)).					
9. 🗌	The brief does not contain copies of the decisions rendered by a court or the Board in the proceeding identified in the Related Appeals and Interferences section of the brief as an appendix thereto (37 CFR 41.37(c)(1)(x)).					
10.🛛	Other (including any explanation in support of the above items):					
	The Appeal Brief filed on May 26, 2006 acknowledge entered. However, Applicant has presented argume See pages 15-18 of the Appeal Brief. Applicant is acafter the final action, but before or on the date of filito provide a showing of good and sufficient reasons earlier presented. See 37 CFR 1,16(e).	ents in the Appeal Brief that have no dvised that the affidavit or other evide ing a Notice of Appeal will not be ent	ot been previously considered. ence, e.g.new arguments filed ered because Applicant failed			